University Hospitals Plymouth
NHS Trust

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[redacted]

16th June 2021

Mr I Arrow
HM Coroner
1 Derriford Business Park
Breast Road
Plymouth
PL6 5QZ

Dear Mr Arrow

Re: Elsie Woodfield

I write further to the inquest into Mrs Woodfield's death, which concluded on 8 June 2021. This letter deals with concerns raised by the family in submissions to the Coroner with regard to his duty to write a Prevention of Future Deaths report to the Trust.

In an email dated 10th June 2021 from [redacted] family concerns were summarised:

- The divergence in terms of consenting process/content for endoscopy processes between [redacted] and [redacted] with one saying they never advise of fatal complications and the other saying they always do.
- The sip test intervention was indicated according to the evidence of [redacted] but was not done.
- An unidentified doctor saw the endoscopy report on the ward and took no action. It was never established who that doctor was and so it has not been explored as to whether steps need to be taken to prevent a recurrence.

- Record keeping concerns. A number of clinicians had failed to maintain proper record keeping and it seems these issues were not explored further once recognised.

Divergence in terms of consenting process

The issue of consent regards death as a possible outcome of this endoscopy procedure has evolved over the last few years. As explained by [redacted] in his evidence, death is not an expected outcome and is rare. Therefore, many clinicians would not have included death when obtaining patient consent. The law following the case of [redacted] now suggests that all 'material risks' should be discussed with a patient i.e. anything they feel would be important to know as a possible outcome. Previously, what was considered appropriate to discuss with a patient when obtaining consent was interpreted as being on the basis of what a significant body of opinion might say.

Currently the plan of the organisation is to move to procedure specific consent where possible and appropriate. We are looking to engage with external providers who produce consent and procedural information that are specific to particular procedures. In that way, rather than individual clinicians using their clinical discretion as to what to discuss with patients, standardised information is given each time a patient consents, ensuring all material information is given. For those undergoing elective surgery, it also allows more time for patients to read at their leisure the information provided, so they have time to digest and absorb the relevant information before signing to say they would wish to proceed.

The current consent guideline at UHP is in line with the British Society of Gastroenterologists (BSG) 2016 and does not expressly the mention mortality[1]. However after consultation with the Endoscopy stakeholders and learning from other incidents, University Hospitals Plymouth has amended the procedure specific consent forms to include:

> *Although very rare, complications arising from endoscopy procedures can result in death particularly if there are other significant health related problems.*

In endoscopy there have been procedure specific consent forms since 2008, which have pertinent information. The updating of the procedure specific consent form has been particularly important as this is provided to patients in advance of their procedure and in advance of talking to the endoscopist on the day. Inpatients (patients that have come through the emergency care pathway) are provided with this information on the ward and it is also reinforced by endoscopy nurses prior to entering the procedure room.

The ward consultants looking after upper gastro-intestinal bleed patients like Mrs Woodfield are senior gastroenterologists and endoscopists. One of the main reasons the Trust has a gastroenterologist specialty medical take is that these individuals are experienced in assessing risk of the procedure versus the risk of not undergoing the procedure, e.g. assessing urgency and appropriateness. In the vast majority of cases there is good evidence that early endoscopy improves outcome and is instrumental to the management of patients with upper GI bleeding in particular those with significant comorbidities (High Rockall scores) and those on anticoagulants. This is discussed with patients prior to referring for endoscopy (and as such is part of the consenting process) and is usually a straightforward discussion but may be more detailed where there are patient specific concerns. The documentation of this discussion in the notes should certainly be improved. Occasionally a decision will be made not to proceed to endoscopy after discussion with patients and next of kin where the risks outweigh the benefits. The documentation of this 'not treating' is largely on the whole better than when the decision is 'for treatment' and is one of the learning points.

[1] BSG (2016) – Guideline for obtaining consent for Gastrointestinal endoscopy procedures

The most pertinent passage from the 2016 national guidance is this:

> *The test of materiality is procedure, circumstance and patient-specific. The test must be patient-centred, since the risk that can influence a patient's decision can vary from one patient to the next and requires careful judgement and individual discussion. Thus, it is beyond the scope of this document to describe in detail the information in relation to risks, benefits or alternatives that should be provided for specific endoscopic procedures. Similarly, it is not possible to state in this guideline whether specific risks should be mentioned or in numerical terms what level of risk should be described. In general, however, you must tell patients if the procedure might result in a serious adverse outcome, even if the likelihood is very small, and mention less serious side effects or complications if frequent. Any risk that is likely to influence the decision of a patient should be included. It is important that in meeting these requirements, the patient is not overwhelmed with excessive information, such that they are unable to evaluate the material risks and benefits.*

The sip test intervention

The use of 'sip' checking, i.e. drinking a small amount of water post oesophago-gastro-duodenoscopy (OGD) is to indicate that patients are able to swallow and do not aspirate liquid into the lungs before being allowed to eat. This is part of basic care and doesn't constitute a diagnostic procedure, merely an aid to support post recovery after an OGD. The sip check is not a test to exclude perforation and the small volume of fluid would not result in mediastinitis.

An unidentified doctor saw the endoscopy report on the ward

The only medical professionals involved with Mrs Woodfield's care on the ward included the consultant, [redacted], and two junior doctors, [redacted] and [redacted]. [redacted] did produce a recollection of events when the organisation received the complaint letter, which did not refer to him having reviewed the endoscopy report. As I said when giving evidence at the inquest, if the incident had been addressed as a SIRI at the outset, the relevant staff would have been interviewed at the time, when memories were fresh, and the doctor who reviewed the endoscopy report would have been identified.

Record keeping concerns

The Trust accepts that elements of the record keeping were poor in this case. All professional bodies have an expectation that individual practitioners will document in the clinical records to an accepted standard. The Trust also has a policy that reflects this expectation. This highlights that responsibility lies with the individual professional and the Trust expects that each individual documents in the health records in accordance with the Trust's policy and in line with codes of practice set by professional standards. Nevertheless, the Trust recognises that documentation may suffer during intense working periods and therefore we regularly remind staff at induction and through mandatory training the importance of proper documentation.

Clear and regular documentation is part of the induction pack given to juniors working within Gastroenterology (see extract below).

> *Clinical notes (Gastroenterology junior doctor induction pack)*
>
> - *Ideally, each notes entry should start with a diagnosis or a short list of differential diagnoses/problems, followed by a management plan for*

investigation, monitoring and treatment. Record all observations numerically – it shows you have actually looked at them, including respiratory rate as this is often the first thing to "go off" if patients get sick.

- *Write in the notes daily when the patient is reviewed.*
- *Document the reasons behind decision making on ward rounds.*
- *Record DNR decisions and if relevant, how intensively to treat a patient eg patient for non-invasive ventilation but not for ventilation or ICU.*
- *Document discussions with relatives ideally recording their names & relationship to the patient*
- *Write the results of blood tests in the notes or update the flow charts for selected patients daily.*
- *Indicate whether investigations have been requested or are planned, but are not yet reported in the notes.*
- *Take results of current in-patients which you sign to the appropriate wards during ward round (otherwise results often don't get into the notes during patient's stay and subsequent transfers of care).*
- *Notes can be used as legal documents. Make entries appropriately and do not back-date clinical entries.*
- *Stick in a week-end plan for all patients every Friday. This is essential and is regularly audited.*
- *Ensure patients have an estimated date of discharge documented.*

The Trust accepts that poor record keeping should have been discussed with the individuals at the time of the event to ensure reflective learning. The revised SIRI process will ensure that any similar issues that may arise in the future would be addressed immediately.

Yours sincerely

[redacted], Chief Nurse & Director of Integrated Clinical Professions

University Hospital Plymouth NHS Trust